K062607

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

TRUREPAIR BONE GRAFT SUBSTITUTE
Date Prepared: ***November 7, 2007***

NOV 0 9 2007

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover, MA 01810

B. Company Contact

Deana Boushell
Principal Regulatory Specialist
(508)337-4036

C. Device Name

Trade Name: TRUREPAIR™ Bone Graft Substitute
Common Name: Bone Graft Substitute
Classification Name: Resorbable calcium salt bone void filler device

D. Predicate Devices

The Smith & Nephew TRUREPAIR Bone Graft Substitute is substantially equivalent in Intended Use and Scientific Technology to the following legally marketed device in commercial distribution: K030288 PolyGraft BGS

E. Description of Device

TRUREPAIR™ implants use the PolyGraft technology and are porous, resorbable scaffolds composed of polylactide-co-glycolide (PLG) copolymer and calcium sulfate. The copolymer is amorphous (noncrystalline) and resorbs in four to twelve months, depending on shape and location. The device also contains Polyglycolide (PGA) fibers and a surfactant . See chart below for available shapes and sizes.

Product Name	Shape	Size Range
TruGraft	Granules	3 – 30 cc
TruFit	Plug	3 – 11 mm diameter 18mm length
TruBlock	Block	15 – 25 mm width 15 – 25 mm height 10 – 20 mm length
TruWedge	Wedge	5 – 15 ° angle 5 mm–15mm height

F. Intended Use

The TRUREPAIR™ Bone Graft Substitute is to be used to fill bony voids or gaps caused by trauma or surgery that are not intrinsic to the stability of the bony structure. The TRUREPAIR™ Bone Graft Substitute is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

G. Comparison of Technological Characteristics

	Polygraft BGS	**TRUREPAIR**
Indications For Use	The Polygraft BGS is to be used to fill bony voids or gaps caused by trauma or surgery that are not intrinsic to the stability of the bony structure. The PolyGraft ™ BGS is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.	Same
Materials	polylactide-co-glycolide (PLG); Calcium Sulfate	Same
Available Shapes	Granules, cubes, blocks, wedges and single phase plugs	Granules, cubes, blocks, wedges and dual phase plugs
Available Sizes	Up to 15cc by volume	Same (See device description for available shapes & sizes)
Packaging/Shelf Life	PETG Tray w/ Tyvek Lid in Poly Tyvek Bag / 2 year shelf life	Same
Sterilization	EO	Same

H. Summary Performance Data

The currently marketed TruRepair Product line is substantially equivalent to the PolyGraft BGS. There have been no changes to indications for use, materials, shelf life, sterilization or packaging. Performance testing conducted includes bench and animal studies that demonstrate substantial equivalence to the PolyGraft BGS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 9 2007

Smith & Nephew, Inc.
Endoscopy Division
c/o Ms. Deana Boushell
Principal Regulatory Specialist
150 Minuteman Rd.
Andover, MA 01810

Re: K062607
Trade/Device Name: TRUREPAIR Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler
Regulatory Class: Class II
Product Code: MQV
Dated: August 10, 2007
Received: August 13, 2007

Dear Ms. Boushell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

The safety and effectiveness of this device for use in osteochondral defects have not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062607

Device Name: TRUREPAIR Bone Graft Substitute

Indications For Use:

The TRUREPAIR™ Bone Graft Substitute is to be used to fill bony voids or gaps caused by trauma or surgery that are not intrinsic to the stability of the bony structure. The TRUREPAIR™ Bone Graft Substitute is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Prescription Use_X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)